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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/582,861	01/16/2007	Nobuo Sakaguchi	4456-0109PUS1	5960

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EXAMINER	
SNYDER, STUART	

ART UNIT	PAPER NUMBER
1648	

NOTIFICATION DATE	DELIVERY MODE
03/20/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary	Application No.	Applicant(s)	
	10/582,861	SAKAGUCHI ET AL.	
	Examiner	Art Unit	
	STUART W. SNYDER	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 November 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14* is/are pending in the application.

4a) Of the above claim(s) *7,9 and 10* is/are withdrawn from consideration.

5)☒ Claim(s) *5 and 8* is/are allowed.

6)☒ Claim(s) *1-4,6 and 11-14* is/are rejected.

7)☒ Claim(s) *1 and 4* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *14 June 2004* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/14/2006 & 9/12/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I in the reply filed on 11/17/2009 is acknowledged. The traversal is on the grounds that the Examiner misapplied PCT rule 13.1 "Lack of Unity" requirements. This is not found persuasive because Applicants' argument that the "special technical feature", a **high affinity** antibody that binds to HIV gp120, is novel and present in claims 1 and 5; Applicants assert that it is the relatively high affinity explicitly recited in claim 1 and intrinsic in GANP collected antibodies. This is not convincing because of general knowledge of the existence of such antibodies in the art as early as 1992 (see, Laman, *et al.*, especially Figure 1 and Boudet, *et al.* 1994, especially "Results" section beginning on page 177). Thus, high affinity antibody specific to the V3 loop were known in the art and the presently claimed invention is not novel.

   The requirement is still deemed proper and is therefore made **FINAL**.

2. Claims 1-6, 8, and 11-14 are pending and examined herein; claims 7, 9 and 10 are withdrawn.

3. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship

must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Drawings

4. New corrected drawings in compliance with 37 CFR 1.121(d) are required in this application because of the following:

The upper panel of Figure 1 is unintelligible.

Applicant is advised to employ the services of a competent patent draftsperson outside the Office, as the U.S. Patent and Trademark Office no longer prepares new drawings. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

Claim Objections

5. Claim 1 is objected to because of the following informalities: Claim 1 recites "a dissociation constant (KD) value of 1.0×10^{-9} (M)". With respect to "(KD)", the use of the abbreviation is unnecessary since the dissociation constant in not found in subsequent claims. Also, the units of K_d are M, not (M). Appropriate correction is required.

6. Claim 4 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 4 recites "wherein the antibody is a polyclonal or monoclonal antibody". The

Examiner is unaware of any other types of antibodies besides polyclonal or monoclonal antibodies. Thus, the recitation fails to further limit claim 1.

Claim Rejections - 35 USC § 112

7. Claims 5 and 8 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. It is apparent that the anti-NL43 monoclone No. G2-25 hybridoma cells deposited as FERM BP-08644 are required to practice the claimed invention because such a requirement is explicitly recited in each claim. As a required element it must be known and readily available to the public or obtainable by a repeatable method set forth in the specification, or otherwise readily available to the public. If it is not so obtainable or available, the enablement requirements of 35 U.S.C. § 112, first paragraph, may be satisfied by a deposit of the aforementioned cells. See 37 CFR 1.802.

The specification does not provide a repeatable method for obtaining anti-NL43 monoclone No. G2-25 hybridoma cell and it is not apparent if it is readily to the public. Applicant's deposit statement on specification page 2 does not indicate the extent of public availability. If the deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the

deposit has been made under the terms of the Budapest Treaty and that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent, would satisfy the deposit requirements. See 37 CFR 1.808.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1-4 and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Laman, *et al.* The claims are drawn to an antibody or fragment thereof which is capable of binding to gp120 and has a dissociation constant value of 10^{-9} M or less. Additional limitations of the claims are that it recognizes a portion of gp120 known in the art as the third variable loop (V3) (claim 2), a specific sequence that encodes one version of V3 (claim 3), the clonal nature of the antibody (claim 4), and a method using the antibody to detect HIV (claim 13).

Laman, *et al.* teaches that one may produce polyclonal antibodies in rabbits and rabbits that have specificity to the V3 loop of HIV-1_{IIIb} by using peptides specific to that region. Laman, *et al.* further teaches that at least one monoclonal antibody (IIIB-V3-13) derived from mice possesses a dissociation constant of 6.8×10^{-11} M (see "Immunochemical characterization of anti-V3 antibodies" and Figure 1 on

page 1825). Laman, *et al.* teaches use of the antibodies in syncytia-formation inhibition assays using cells and virus known to exhibit syncytia formation (p 1826); this method indirectly detects HIV because only virus not bound and neutralized by antibody infects cells and subsequently forms syncytia. Laman, *et al.* teaches the use of antibodies in flow cytometry and immunocytochemical detection of HIV-1 infected cells (see Figures 4 and 5, respectively on page 1828 and discussion beginning on p 1825); each of these methods detects virus infected cells.

Thus, each and every limitation of claims 1-4 and 13 is taught by Laman, *et al.* which clearly anticipates the instantly claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Laman, *et al.* The relevance of Laman, *et al.* is set forth above in section 7. Laman, *et al.* does not explicitly teach a does not teach a kit for performing a diagnostic assays *in vitro* of enteroviruses. However, it is well known in the art of immunology that simply packaging the reagents and supplies that are necessary for performance of a diagnostic assay together does not give unexpected results for the assay but rather gives known expected results. One of ordinary skill in the art of

immunology is motivated to assemble the reagents in a kit for ease of use and perhaps commercial gain. Thus, it would have been obvious for one of ordinary skill in the art of immunology to combine the reagents necessary to practice the method of Laman, *et al.* to achieve the expected results of the assay.

10. Claims 6, 11, and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Laman, *et al.* in view of Okamoto, *et al.* Claims 6, 11 and 12 are drawn to compositions comprising a humanized high affinity antibody and pharmaceutical compositions thereof. The teachings of Laman, *et al.* are summarized above in section 7; Laman, *et al.* does not teach humanization of antibodies. Okamoto, *et al.* teaches preparation and use of a humanized monoclonal antibody directed to HIV-1 gp120 V3 loop as a therapeutic that was administered to SCID-Hu mice. Such administration prevented infection by subsequent challenge and pathogenic consequences thereof.

It would have been obvious for a skilled artisan to humanize antibodies derived from non-human sources and directed to a major HIV neutralization determinant to arrive at the instantly claimed invention. As taught by Okamoto, *et al.* the skilled artisan would have been motivated to humanize a potentially therapeutic antibody for subsequent passive immunization of humans (see discussion, especially p 75). The skilled artisan would have expected success in preparing an antibody using the methods of Okamoto, *et al.* to humanize a high affinity antibody to HIV-1 gp120 V3 loop because of the universality and versatility of the

method. Thus, the invention of claims 6, 11, and 12 was clearly *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Allowable Subject Matter

11. Claims 5 and 8 would be allowable if the rejection(s) under 35 U.S.C. 112, 1st paragraph, set forth in this Office action is overcome.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to STUART W. SNYDER whose telephone number is (571)272-9945. The examiner can normally be reached on 9:00 AM-5:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce R. Campell can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.
Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Mary E Mosher/
Primary Examiner, Art Unit 1648

Stuart W Snyder
Examiner
Art Unit 1648

sws